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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/117.586	07/31/98	BAILEY	S 87647.98R199
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EXAMINER

PRATT, H

ART UNIT

PAPER NUMBER

1761

DATE MAILED:

04/22/99

#10

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/117,586

Applicant(s)

Bailey et al.

Examiner

Pratt, H.

Group Art Unit

1761

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 7-7-98  
Prelim. Amnt 1-19-99
- ☒ Responsive to communication(s) filed on Prelim. Amnt 1-19-99.
  - ☐ This action is **FINAL**.
  - ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 45-111
- ☒ Claim(s) 45-111 is/are pending in the application.
  - Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
  - ☐ Claim(s) 45, 50-54, 57, 58, 67, 73, 83-85, 96-98, 99-102, 103 is/are allowed. 108, 109
  - ☒ Claim(s) 46-48, 49, 55, 56, 62-66, 68, 69-72, 74-79, 86-89, 90-92, 104, 107, 110, 111, 93-95 is/are rejected.
  - ☐ Claim(s) \_\_\_\_\_ is/are objected to.
  - ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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### DETAILED ACTION

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46-49, 55, 56, 62-66, 68, 69-72, 74-79, 86-89, 90-95, 104-107, 110, 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. or Shimoda et al. in view of Pedersen et al., Lucas et al., and Mueller et al.

Mueller et al. disclose a composition containing 5-methyl-9S)-tetrahydrofolic acid and 5-10 methyl-(6S) tetrahydrofolic acid. See abstract. Also, Shimoda et al. disclose a composition containing vitamins in particular amounts and natural reduced folates (col. 4, lines 3-17, col. 7, lines 61-65). Claims 49 and 56 differ from the references in the use of the folate with a nutritional substance which is a vitamin in particular amounts. However, Pedersen et al. disclose that it is known to use folacin in a potato flake. See col. 6, lines 1-12. Lucas et al. disclose that it is known to use folic acid in an infant food. The specification discloses that these substances are broken down in the digestive tract to the reduced form by an enzyme (col. 5, lines 9-16). If it is known that folic acid and folacin are broken down to make the claimed compositions, then it is obvious that such natural compounds can be also eaten in foods. The references, Pedersen et al. and Lucas et al., are seen to be cumulative to show an improvement in the art. Applicants admit in the specification that 5 formyl-tetrahydrofolic acid and 5 methyl-tetrahydrofolic acid have been

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used in therapeutic doses. See page 5, lines 17-24. Mueller et al. disclose that their invention is an improvement of 6S and R forms with a natural form of 6S(col. 2, lines 3-7). Certainly, it would have been obvious to use a vitamin type substance with other foods, as food enrichment is well known and vitamins are rarely taken alone except as in pills. Therefore, it would have been obvious to one of ordinary skill in the art to use a reduced folate with other vitamins in the claimed composition.

The further limitations of claims 62-66 as to the addition of essential nutrients, the isomer being chirally pure and the particular natural isomers are seen to have been shown by the reference as above or are inherent characteristics. Therefore, it would have been obvious to add the ingredients of above to make the claimed composition.

Claims 68, 69, 74 and 75, 76 further require that the composition is only for particular animals and not pigs. However, nothing has been seen that the composition would not have worked for pigs which are also mammals, of course and no reason is seen for excluding them except to exclude the reference to Shimoda et al. The further limitation of adding less amounts of unnatural isomers of reduced folate is not seen to add patentable weight to the claims in that no reason is stated for such amounts nor is the addition of ascorbic acid to the composition which is a well known nutrient usually added for its known functions and nothing is seen that it adds any unobvious or unexpected results to the composition. The further limitations of the claims have been discussed above and are obvious for those reasons.

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*Specification*

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should also indicate the method.

*Allowable Subject Matter*

2. Claims 45, 50-54, 57, 58, 67, 73, 83-85, 96-98, 99-102, 103 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Pratt whose telephone number is (703) 308-1978. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. David Lacey, can be reached on (703) 308-3535. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3602 (unofficial faxes), **after final faxes 703 305 3599, and other official faxes 703 305 7718.**

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
HELEN PRATT

PRIMARY EXAMINER

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